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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,845	01/26/2006	Jadwiga Bienkowska	ARS-113	2205

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EXAMINER	
MACFARLANE, STACEY NEE	
ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
12/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,845	BIENKOWSKA ET AL.	
	Examiner	Art Unit	
	STACEY MACFARLANE	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *57-82* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *57-82* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. Claim 73 has been amended as requested in the amendment filed on October 10, 2008. Following the amendment, claims 57-82 are pending in the instant application.

Claims 57-82, in so far as they are drawn to the elected SEQ ID NO: 2, are under examination in the instant office action.

2. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

3. Applicant's arguments filed on October 10, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

4. Claims 57-82 stand as rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility, for reasons of record in the Office action mailed July 31, 2008.

On pages 13-15 of Remarks filed October 10, 2008, Applicant traverses the rejection on the grounds that the specification sets forth the following as asserted utilities:

> "Applicants also note that the as-filed specification indicates (at page 5, lines 16-26):
>
> The novel polypeptide described herein was identified on the basis of a consensus sequence for human Preadipocyte factor-1-like polypeptides in which the number and the positioning of selected amino acids are defined for a protein

> sequence having a length comparable to known Preadipocyte factor-1-like polypeptides.
>
> The totality of amino acid sequences obtained by translating the known ORFs in the human genome were challenged using this consensus sequence, and the positive hits were further screened for the presence of predicted specific structural and functional "signatures" that are distinctive of a polypeptide of this nature, and finally selected by comparing sequence features with known Preadipocyte factor-1-like polypeptides. Therefore, the novel polypeptides of the invention can be predicted to have Preadipocyte factor-1-like activities".

Applicants further traverse that the evidence presented in Wilson et al. teach that with sequence identity of 30%, polypeptides are "virtually certain to have the same fold, [and] the polypeptide has 66% likelihood of having the same exact function." Thus, Applicant concludes that by having 34% identity and 46% similarity would indicate that the claimed polypeptide is more likely than not to have the same function as Preadipocyte factor-1-like polypeptides. While these arguments have been carefully considered they are not found persuasive for the following reasons.

As stated in the previous Office action mailed July 31, 2008, the assert utilities for these polypeptides, which are based upon domain organization, are that they "may interact with integrin cell surface receptors, which are involved in cell adhesion" or "may act as integral SCS0009 antagonist in vivo". Thus, the asserted functions of the polypeptide are merely hypothetical and are not specific utilities to the claimed subject matter. There is no supporting evidence of either functional analysis or specific tissue expression for the polypeptides of the invention. Sequence comparisons do not provide support for specific function and the specification merely suggests further experimental investigation (i.e. "metabolic endocrinology assays suitable for exploration of the

biological relevance of protein function") to determine the activity of the claimed polypeptides. None of the teachings within the specification meet the requirement for a substantial real-world utility. Instead, they are merely invitations for further research to identify or reasonably confirm a "real world" context of use for the claimed polypeptides. Therefore, the rejection is maintained.

Claims 57-82 also stand as rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 57, 64-69 and 77-82 stand as rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record in the Paper mailed July 31, 2008.

On pages 15-17 of Remarks filed October 10, 2008, Applicant traverses the rejection on the grounds that, "the claims provide at least a partial structure of the claimed polypeptide variants; namely, any one of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 8, SEQ ID NO: 9 or SEQ ID NO: 10 in which no more than 15% of the amino acid residues are substituted and wherein the polypeptide retains the ability

to prevent the terminal differentiation of preadipocytes". Applicant further submits that the domain of PREF-1 associated with the claimed activity was known in the art at the time of filing and present the Smas et al article as evidence. Applicant conclude that the as-filed specification fully comply with the written description requirement because the structures are already known in the art. While this argument has been considered in full, it is not found persuasive to overcome the rejection on the following grounds.

Briefly claims encompass active variants of the instantly-elected SEQ ID NO:2 that serve the activity of preventing the terminal differentiation of preadipocytes in which no more than 15% of the residues are substituted, dependent claims do not further limit the "variants", and are therefore included in the rejection. While the domain that accounts for said activity may have been known in the art, the claims are drawn to variants with up to 15% substituted residues and merely require that these variants retain said activity. Thus, the claims are drawn to a genus of molecules merely defined by function and the instant specification fails to describe the entire genus of molecules that are encompassed by these claims.

Applicant is reminded that the requirement for written description under the first paragraph of section 112 is separate and distinct from the enablement requirement of that paragraph. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991). Compliance with the written description requirement is a question of fact. *Id.*

"A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure,

formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. EliLilly and Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1405 (Fed. Cir. 1997 (bracketed material in original). The claims in *Lilly* were directed generically to vertebrate or mammalian insulin cDNAs. See *Id* at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs.

This standard applies to peptides as well as DNAs. *See University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916, 925, 69 USPQ2d 1886, "893 (Fed. Cir. 2004): "We agree with Rochester that *Fiefs, Lilly*, and *Enzo* differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester's position. It is irrelevant; the statute applies to all types of inventions. We see no reason for the rule to be any different when non-genetic materials are at issue."

With respect to the use of a functional assay to support written description, in *University of Rochester*, the court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of *which* peptide molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. *See id.* ("As pointed out by the district court, the '850 patent does not disclose just 'which "peptides, polynucleotides, and small organic molecules" have the desired characteristic of selectively inhibiting PGHS-2.'... Without such disclosure, the claimed methods cannot be said to have been described.").

The Examiner has found that the instant disclosure as filed does not provide adequate written description to support the genus of molecules encompassed within the genus claimed, namely active peptide variants of SEQ ID NO:2 in which up to 15% of the residues have been substituted. Furthermore, the specification does not disclose said substituted variants as having a conserved structure-to-function correlation for maintaining the capability of performing said activity. Therefore, just as in *University of Rochester*, the present specification does not disclose which polypeptides having up to 15% residue substitutions within SEQ ID NO: 2 fulfill the functional limitation.

Granted, those skilled in the art could screen libraries of peptides having 15% residue substitutions to SEQ ID NO: 2, but that, however, does not make up for the deficiency of the specification's description. The *University of Rochester* court specifically noted that the patent at issue there disclosed screening assays to identify compounds having the desired characteristic, but nonetheless held that the description was inadequate. The same holds true here. Thus, the rejection is maintained.

Conclusion

7. No claim is allowed.

8. This application contains claims drawn to an nonelected subject matter elected with traverse in Paper filed on April 14, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STACEY MACFARLANE whose telephone number is (571)270-3057. The examiner can normally be reached on M-W and ALT F 5:30 to 3:30, TELEWORK-Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Stacey MacFarlane
Examiner
Art Unit 1649

/John D. Ulm/
Primary Examiner, Art Unit 1649